LITE DEPALMA GREENBERG, LLC
Allyn Z. Lite
Mayra V. Tarantino
Two Gateway Center, Suite 1201
Newark, NJ 07102
(973) 623-3000
alite@litedepalma.com
mtarantino@litedepalma.com

Attorneys for Defendants and Counterclaim-Plaintiffs Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd.

IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 11-760 (JAP)(TJB)

Hanmi's Motion *in Limine* No. 3
(To Preclude AstraZeneca From Attempting To Establish a Filing Date for the '192 Patent Earlier Than April 11, 1997)

Hanmi hereby moves *in limine* to preclude AstraZeneca from seeking to establish through evidence or argument an effective filing date of asserted U.S. Patent 5,877,192 ("the '192 patent") (D.I. 111-9), for any asserted claim that is earlier than the actual filing date of April 11, 1997.

A. Background Facts and Burden of Proof

In its invalidity contentions and opening expert reports, Hanmi established a *prima facie* showing of anticipation of each asserted claim of the '192 patent, based on WO 94/27988 ("WO '988"). (*See* D.I. 87-1,Hanmi's May 25, 2011 Non-infringement and Invalidity Contentions pursuant to L. Pat. R. 3, pp. 121 -131 (including element-by-element claim charts); *see also* Ex. 15, Expert Report of Jerry L. Atwood, Ph.D., dated February 19, 2013, ¶¶ 155-202 and Exhibit 5 of Atwood Expert Report (claim charts)).

U.S. Patent Application No. 08/833,962 ("the '962 application"), which issued as the '192 patent, was filed April 11, 1997 as a continuation-in-part application. (*See* D.I. 111-9, '192 patent, cover page). WO '988 bears a publication date of December 8, 1994. (D.I. 110-2, WO '988 at HAN0039134). WO '988 was published more than one year before the filing date of the '192 patent, and therefore qualifies as a statutory bar reference pursuant to 35 U.S.C. § 102(b) – unless *AstraZeneca* can show that the claims at issue are entitled to an earlier filing date pursuant to 35 U.S.C. § 120. *See PowerOasis, Inc. v. T-Mobile USA, Inc.,* 522 F.3d 1299, 1305-1306 (Fed. Cir. 2008) (once a challenger has met its burden of coming forward with invalidating prior art, patentee bears the burden of coming forward with evidence to prove entitlement to an earlier filing date).

AstraZeneca has never challenged Hanmi's position that, on the assumption that WO '988 is prior art to the '192 patent, each asserted claim of the '192 patent is anticipated and

invalid in view of WO '988. In other words, AstraZeneca failed to provide any evidence or any other basis (*i.e.*, AstraZeneca's Responses to Hamni's Invalidity Contentions or AstraZeneca's expert reports) to rebut Hanmi's position that WO '988 anticipates the asserted claims of the '192 patent.

For example, in responding to Hanmi's *prima facie* showing of anticipation, AstraZeneca's contentions failed to show legal entitlement to a filing date earlier than April 11, 1997 on a claim-by-claim basis. (*See* Ex. 31, AstraZeneca's Amended Responses to Hanmi's Invalidity Contentions Pursuant to N.J. Loc. Pat. R. 3.6(i) and 3.7, dated March 19, 2012, at pages 76-81, only discussing several claim terms.)

B. Argument

There can be no dispute that each of the prior applications listed on the cover page of the '192 patent has a different disclosure than the '962 application, as filed on April 11, 1997 and later issued as the '192 patent; the '962 is a "continuation-in-part" of the parent '512 application, which itself was a "continuation in part" of its parent '174 application. (*See* D.I. 111-9, '192 patent, cover page.)

Among other things, establishing entitlement to an earlier filing date requires showing that ***the subject matter of each claim is disclosed in a prior application*** in the manner required by 35 U.S.C. § 112, first paragraph. *See* 35 U.S.C. § 120; *Anascape, Ltd. v. Nintendo of Am., Inc*., 601 F.3d 1333, 1335 (Fed. Cir. 2010) ("To obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent 'in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought,'" citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

Although it is not Hanmi's burden to "disprove" entitlement to an earlier filing date,[1] Hanmi's contentions (cited above) and expert reports provide several reasons why certain aspects of the '192 claims could not be shown by AstraZeneca to be disclosed in prior applications. *See, e.g.*, Ex 15, Expert Report of Jerry L. Atwood, Ph.D., dated February 19, 2013, ¶¶ 159-184. AstraZeneca's experts have purported to respond to those specific points (Drs. Levy, Johnson, Davies), but nowhere has AstraZeneca made a showing as to where in each prior application the specific subject matter of each asserted claim is found on a limitation by limitation basis. Accordingly, AstraZeneca should not be permitted to try to do so for the first time at trial. This conclusion is in accord with the well-established principle of civil litigation that the scope of an expert's opinions at trial is limited to the opinions disclosed in that expert's report. *See, e.g.*, *O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1368-69 (Fed. Cir. 2006) (affirming district court's exclusion of expert opinions concerning matters not disclosed in the opening expert reports). *See also Northlake Mktg & Supply, Inc. v. Glaverbel, S.A.*, No. 92 C 2732, 1996 U.S. Dist. LEXIS 19306, at *5-6, *11 (N.D. Ill. Dec. 17, 1996) (granting motion *in limine* to exclude expert from testifying on matters not set out in his initial report).

Even AstraZeneca's "partial" showings in its experts reports are deficient. As one example, with respect to the claim limitation "proton pump inhibitor" recited in each asserted '192 claim, Dr. Johnson's report included a section entitled "The Proton Pump Inhibitor Is Adequately Disclosed In Both The Specification And The Three Earlier Applications." *See* Ex 7, Rebuttal Report of Dr. David A. Johnson on Validity, dated March 25, 2013, ¶¶ 70-79.

[1] *See PowerOasis*, 522 F.3d at 1305-1306 (affirming the district court's holding that "when a dispute arises concerning whether a CIP patent is entitled to priority to the date of the original application and the Patent Office has not addressed the issue, the burden of proof ordinarily should rest with the party claiming priority to the date of the original application").

However, during his April 18th deposition, when shown the three earlier applications and asked to explain where the claim term "proton pump inhibitor" was described, Dr. Johnson demurred, indicating that was a question better left for others. *See* Ex 18, Deposition of David Johnson, MD, April 18, 2013 at pp. 125-130.

Thus, since AstraZeneca does not have a witness to provide trial testimony to support even its incomplete effort to satisfy disclosure of "proton pump inhibitor" in any prior application, Hanmi's motion to preclude AstraZeneca from seeking to establish an earlier filing date for any asserted claim of the '192 patent should be granted. Any other result renders virtually meaningless the well-structured procedures of discovery through contentions and expert discovery established in this Court for the orderly – and fair – adjudication of patent disputes.

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LITE DEPALMA GREENBERG, LLC

s/Mayra V. Tarantino
Allyn Z. Lite
Mayra V. Tarantino
Two Gateway Center, Suite 1201
Newark, NJ 07102
(973) 623-3000
alite@litedepalma.com
mtarantino@litedepalma.com

SUGHRUE MION, PLLC
Mark Boland
Michael R. Dzwonczyk
Renita S. Rathinam
2100 Pennsylvania Ave., NW
Washington, DC 20037-3213
(202) 293-7060

mboland@sughrue.com
mdzwoncyzk@sughrue.com
rrathinam@sughrue.com

John B. Scherling
4250 Executive Square
Suite 900
La Jolla, CA 92037
(858) 795-1180
jscherling@sughrue.com

Attorneys for Defendants and Counterclaim-Plaintiffs Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2013, I caused a copy of the foregoing **Hanmi's Motion in Limine No. 3 (To Preclude AstraZeneca From Attempting To Establish a Filing Date for the '192 Patent Earlier Than April 11, 1997)** to be served upon the following counsel by electronic mail:

John E. Flaherty, Esq.
Jonathan M. H. Short
McCARTER & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444
JFlaherty@mccarter.com
JShort@mccarter.com

Einar Stole
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000
EStole@cov.com

Henry J. Renk
Bruce C. Haas
Colleen Tracy
Joshua I. Rothman
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2250
HRenk@fchs.com
BHaas@fchs.com
CTracy@fchs.com
JRothman@fchs.com

s/Mayra V. Tarantino
Mayra V. Tarantino